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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, MONTANA, NEVADA NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA RHODE ISLAND, TENNESSEE, TEXAS, and WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; ex rel. MARC ANDREOZZI Plaintiffs v. ELI LILLY AND COMPANY Defendant.	CV 09 1921 Civil Action No._____ **FALSE CLAIMS ACT COMPLAINT** FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

FALSE CLAIMS ACT COMPLAINT

INTRODUCTION

1. Marc Andreozzi ("Relator") brings this action on behalf of the United States of America against Eli Lilly and Company (hereinafter referred to as "Lilly" or "Defendant") for treble damages and civil penalties arising from Lilly's conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA").

2. This action is also brought under the respective qui tam provisions of False Claims Acts (or similarly named) on behalf of the of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the District of Columbia, the Commonwealths of Massachusetts and Virginia. These states, together with the United States, are hereafter collectively referred to as the Government.

3. The violations arise out of requests for payment by Medicare, Medicaid, TRICARE, and other federally-funded government healthcare programs (hereinafter referred to as "Government Healthcare Programs").

4. This Complaint describes a systematic course of conduct by Lilly to unlawfully promote the prescription drug Cymbalta off-label for chronic pain (to include any and all knee pain, shoulder pain, lower back pain, or any other type of sustained pain anywhere on the human body).

5. Cymbalta is now Lilly's best-selling U.S. product, overtaking antipsychotic Zyprexa (olanzapine) during the first quarter of 2008. In first quarter 2009, Lilly reported sales of Cymbalta increased 17 percent, to $597.1 million.

6. Over the years, Lilly has boasted of its strict purported adherence to strict ethical standards and guidelines. Lilly provided an ethical code to its sales force which was set forth in, among other places, the "Red Book." According to the Lilly's website, the Red Book is a "comprehensive code of ethical and legal business conduct applicable to all employees. " The Red Book contains a section entitled, "Ethical Interactions with Health Care Providers and the Promotion a/Pharmaceutical Products" wherein it states, in relevant part:

> Employees must comply with all laws, regulations, industry codes of practice, company policies, and government and court orders and decrees that govern the promotion of Lilly medicines and medical devices. Employees must also behave ethically in dealings with health care providers.

7. Within the same section of the Red Book, Lilly outlines in relevant part, that employees involved in sales and marketing activities must (among other things):

(a) "Promote Lilly products only for their locally approved indications" and
(b) "Not proactively discuss information about unapproved new products or off-label information."

8. Despite this purported high ethical standards, Lilly has undergone multiple investigations and has settled for large sums of money and criminal penalties, due to allegations of off-label promotion and/or related conduct. They include, in 2005, Lilly settled a federal investigation and pleaded guilty to claims it promoted its bone loss drug, Evista, for off-label use. Lilly paid a total of$36 million in disgorged profits and fines. In January 2009, Lilly agreed to plead guilty and pay $1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration The resolution included a criminal fine of $515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind. Lilly also agreed to pay up to $800 million in a civil settlement with the federal government and the states.

INFORMATION ABOUT THE RELATOR

9. Relator, Marc Andreozzi, is a resident of Florida. He was employed by Lilly as a Neuroscience Sales Specialist from approximately April 2006 until November 2008.

10. Relator brings this action based on his direct knowledge and also on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4). Notwithstanding same, Relator is an original source of the facts alleged in this Complaint.

11. Relator is informed and believes that the pervasive kickbacks and false claims described herein began are ongoing and dates back at least five years.

12. Relator was hired by Lilly to market 4 drugs, one of which was Cymbalta. He was trained by Lilly on methods to market Cymbalta off-label during sales calls with physicians; trained by Lilly about evasive conversational tactics to deflect appropriate questions about Cymbalta's lack of FDA-approved indication for chronic pain, was given articles and studies and other materials to justify Cymbalta's off-label marketing message; and was trained by Lilly to identify and seek out physicians who could be solicited to accept inducements in exchange for writing large volumes of Cymbalta. Relator is personally aware that these same tactics were provided by Lilly on a national basis throughout its salesforce when selling and detailing Cymbalta.

13. Relator has personal knowledge of Lilly's corporate endorsement of this unlawful national off-label Cymbalta marketing scheme for the chronic pain market and also has personal knowledge of the specific Lilly corporate personnel responsible for implementing Cymbalta's off-label marketing.

14. Each District within Lilly was typically made up of a population of a mid-size city, and typically Lilly employed one Manager and 12-14 representatives within each District to call on physicians to prescribe Cymbalta.

15. Relator's territory was the Florida Tallahassee District. Lilly stationed its specialty reps in every state. Lilly recognized that certain states were "most important," and recognized Florida and California, for instance to be "heavyweight" states, to which Lilly assigned relatively large sales forces. Both were known to have high Medicare and Medicaid populations.

16. Lilly organized its Cymbalta sales operations into regional divisions, headed by Enrique Conterno, V.P. of Sales (now President, Lilly USA). The State of Florida fell within Lilly's East division, headed by Greg Beeman, V.P. Neuroscience Sales. Lilly further divided the marketing territories into areas, and then subdivided further into districts.

INFORMATION ABOUT LILLY

17. Defendant Lilly is a pharmaceutical company engaged in the development, manufacturing and marketing of pharmaceutical products. Its headquarters are located in Indianapolis, Indiana, it is an Indiana corporation, and it does business throughout the United States.

18. At all times relevant hereto, Lilly acted through its agents and employees, and the acts of Lilly's agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of Lilly.

FEDERAL JURISDICTION AND VENUE

19. The acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein occurred in part in the Northern District of California, and Lilly does business in the Northern District of California. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a), as well as under 28 U.S.C. § 1345. This Court has jurisdiction over this case for the claims brought

on behalf of the states (referenced in paragraph 2) pursuant to 31 U.S.C. §3732(b), inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claim brought on behalf of the United States.

20. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Lilly transacts business in this District.

THE REGULATORY ENVIRONMENT

The FDCA

21. The United States Food, Drug and Cosmetic Act (FDCA) establishes the framework for regulation of, inter alia, the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. When the United States Food and Drug Administration ("FDA") approves a drug, it approves the drug only for the particular use for which it was tested.

22. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

23. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use, also known as "misbranding," constitutes unlawful promotional advertising of the drug, violates the FDCA, and can also serve as the basis for an FCA violation.

24. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. For example, the FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (B) manufacturer support for Continuing Medical Education ("CME") programs and "speaker" programs, that focus on off-label uses.

25. With regard to the first practice—disseminating written information—the FDCA

allows a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; and has provided the materials to the FDA prior to dissemination. The materials must be submitted in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c);360aaa-1.

26. The promotion of an off-label use for a prescription drug can interfere with the proper treatment of a patient. Off-label promotion can lull a physician into believing that the drug being promoted is safe and effective for the intended off-label use, and that the FDA has approved the drug for that use. Thus, off-label promotion can cause a doctor and patient to forgo treatment with an FDA-approved drug that has been proven to be safe and effective, and instead to substitute a treatment urged by the sales representative that is not known to be safe and effective, and that may in fact be harmful.

Anti-Kickback Act

27. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE.

28. The Anti-Kickback Act is designed to, inter alia, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

29. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

30. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

False Claims Act

31. The False Claims Act (hereinafter referred to as "FCA"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

32. The FCA provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

33. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time). Based on these provisions, qui tam plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

34. The FCA provides, in pertinent part that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;
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> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount

> of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

FEDERAL HEALTHCARE PROGRAMS

35. Federally-funded healthcare programs ("Government Healthcare Programs") cover prescription drugs. The programs include but are not limited to the following three programs.

36. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

37. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. See 42 U.S.C. §§1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. See 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan ..." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

38. TRICARE is the component agency of the U.S. Department of Defense that administers and supervises the health care program for certain military personnel and their dependents. TRICARE contracts with a fiscal intermediary that receives, adjudicates, processes and pays health care claims submitted to it by TRICARE beneficiaries or providers. The funds used to pay the TRICARE claims are federal government funds.

CYMBALTA FDA APPROVAL AND REGULATORY ACTION

39. On November 12, 2001, Defendant Lilly submitted an NDA seeking approval of a drug called Cymbalta (also known by the chemical name duloxetine hydrochloride) 20, 30 and 60

mg capsules to treat major depressive disorder and diabetic neuropathic pain. It also later submitted supplemental NDA's for additional indications.

40. Cymbalta has gained FDA-approval for: Major Depressive Disorder (MDD) (approved August 2004), Diabetic Peripheral Neuropathic Pain (DPNP) (approved September 2004) Generalized Anxiety Disorder (GAD) (approved 2007), and Fibromyalgia (FM) (approved July 2008).

41. Two of these indications are pain-related. Fibromyalgia is estimated to affect 2 percent of the U.S. population - approximately 5 million people - the majority of those diagnosed being women. Diabetic Peripheral Neuropathic Pain is estimated to affect less than 10 million persons of the U.S. population.

Suicide and other Dangers

42. In 2005, the FDA announced that Cymbalta was causing more than twice the rate of suicide attempts in women prescribed the drug for stress urinary incontinence -- a use not approved in the U.S.

43. In May 2006, the FDA ordered Lilly to add a black box to Cymbalta warning about suicides and antidepressants in young adults. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

44. Cymbalta is a dangerous drug even when prescribed for on-label use. It is even more dangerous for patients in chronic pain, who already are prone to suicidal ideation.

45. Cymbalta is known to cause a litany of side effects across all age groups. For instance, in October 2005, the FDA announced that postmarketing reports of liver injury suggest that patients with pre-existing liver disease who take Cymbalta may have an increased risk for further liver damages, resulting in a broader warning on Cymbalta's label.

Misleading promotional materials

46. In a letter dated September 9, 2005, the FDA sent Lilly a letter informing the

company that it found the company's promotional materials and activities "to be false or misleading, and in violation of the Federal Food, Drug, and Cosmetic Act." In particular, the FDA cautioned Lilly overstating the efficacy of Cymbalta for DPNP such as the statement, "significantly less pain interference with overall functioning." The FDA also warned Lilly about failing to communicate some of the most serious risks associated with Cymbalta.

47. In October 2006, Lilly was told by the FDA to "immediately cease" its Cymbalta campaign for diabetic nerve pain -- an approved use -- which promised "significantly less pain interference with overall functioning." The FDA said the claim "has not been demonstrated by substantial evidence or . . . clinical experience" nor do the Cymbalta marketing pieces give precautions about liver toxicity or reveal risks for patients with certain conditions.

48. By a letter dated September 21, 2007, the FDA informed Lilly that it found the company's promotional materials and activities "to be false or misleading, and in violation of the Federal Food, Drug, and Cosmetic Act." In particular, the FDA cautioned Lilly about its misleading journal ads which failed to disclose that Cymbalta is "associated with several important risks... but the ads fail to disclose any of these risks within the main parts of the ads."

Lilly submits and then withdraws its application for FDA approval for chronic pain

49. In August 2007, Defendant Lilly submitted a supplemental new drug application for the use of Cymbalta to treat chronic pain. According to a June 2, 2008 Washington Drug Letter article, the Cymbalta sNDA was based on three double-blind, randomized trials -- one testing the drug in 230 patients with chronic osteoarthritis pain of the knee and two testing the product in a total of 630 patients with chronic lower back pain, the company said. The application also included data from previously completed studies in patients with diabetic peripheral neuropathic pain and fibromyalgia.

50. In November 2008, Defendant Lilly withdrew its supplemental new drug application for the use of Cymbalta to treat chronic pain, amidst FDA questions about its efficacy. Lilly has been quoted since then as suggesting it would resubmit its NDA with the results of a new knee study, by mid 2009.

51. Lilly's 2008 withdrawal of the supplemental NDA for chronic pain indication suggest

that Cymbalta is of questionable efficacy at best. It could only have reached the enormous prescription levels it has by misleading sales pitches about its safety and efficacy for chronic pain. This wrongful conduct is excacerbated because it is a drug with serious known adverse events and side effects, which was not disclosed to the sales force (and therefore to physicians) until after the information was publicly known.

LILLY UNLAWFULLY PROMOTED CYMBALTA FOR THE TREATMENT OF CHRONIC PAIN

52. Lilly's management trained and directed its sales force to promote Cymbalta for off-label uses.

53. Lilly began planning its national, aggressive off-label marketing campaign for Cymbalta even before Cymbalta had received FDA approval.

54. Through this planning Lilly funded clinical studies for Cymbalta, for on and off-label uses, which ultimately Lilly planned to be used by its sales representatives to promote Cymbalta. Indeed, Relator was given such studies by Lilly with the expectation that learn the details of the studies backwards and forwards and use the talking points provided by Lilly, in promoting Cymbalta off-label.

55. By focusing on symptoms rather than the diagnoses of DPNP or FM, Lilly intended to overcome Cymbalta's lack of any FDA approved market for Cymbalta in the chronic pain market.

56. Lilly promoted Cymbalta for the treatment of chronic pain, even though Lilly knew that its studies of Cymbalta for the treatment of chronic pain had yielded mixed clinical results, and also knew that Cymbalta had serious risks and side effects.

57. Lilly implemented this off-label marketing campaign targeting pain physicians (certain anesthesiologists and physiatrists), orthopedic surgeons, neurosurgeons, thoracic surgeons and other physicians, even though Lilly knew that there was virtually no on-label use for Cymbalta in these physician markets. Relator received "sample card kits" which listed specific physicians he was to call on, many of which never treated patients for whom Cymbalta's indicated uses were appropriate.

58. Defendant Lilly's off-label promotion of Cymbalta raised safety issues, affected the

treatment of patients, and undermined the FDA drug approval process. Lilly undertook this illegal off-label promotion for its own financial gain, despite the potential risk to patients' health and lives.

59. The promotion has worked: 30-45% of all Cymbalta prescriptions were written for chronic pain, and this is excluding all prescriptions written by psychiatrists (who conceivably could be writing Cymbalta on-label.) Cymbalta's sales were generated from off-label promotion of uses for chronic pain such as post operative pain, cancer break-through pain, lower back pain, and knee pain.

60. Relator's call lists (targets) for Cymbalta included Orthopaedic Surgeons, Neurosurgeons, Neurologists, Anesthesiologists/Pain Management physicians, Pain Management Clinics, Thoracic Surgeons as well as other types of surgeons.

61. All of those physicians were in addition to the on-label targets: Psychiatrists, Primary Care Physicians, Internal Medicine Physicians, Podiatrists, and Rheumetologists (Fibromyalga indication).

62. Anticipating the possibility of resistance from physicians in prescribing Cymbalta for chronic pain, Defendant Lilly specifically trained its sales representatives on how to respond to doctors' concerns about off-label uses of Cymbalta.

63. Defendant Lilly retained doctors to speak to other doctors during peer-to-peer sessions about off-label uses of Cymbalta for various chronic pain states.

64. Through its communications to its sales force and to doctors Lilly deliberately omitted the following critical information:

a. Lilly omitted negative evidence about Cymbalta;

b. Lilly omitted information that virtually all publications and studies that allegedly supported Cymbalta's chronic pain uses had been initiated and funded by Lilly, and those that were not initiated and funded by Lilly were shared with neither sales representatives nor physicians.

c. Lilly omitted information that the doctors who were involved in peer selling had been paid substantial subsidies to use Lilly drugs on their patients for non-medically accepted or non-medically necessary purposes;

d. Lilly omitted information related to dangerous side effects revealed through Lilly's internal research, adverse event reports, and independent research.

65. Through its communications to the sales force and physicians:

a. Lilly suggested mechanisms of action that could explain Cymbalta' s efficacy, safety profile and use for chronic pain even though Cymbalta's mechanism of action are not understood; and even though the explanation was a stretch at best. It trained its sales force to pitch to physicians that since Cymbalta was FDA-approved for DPNP and FM, indications to other pain states, that it was also highly effective for chronic pain.

b. Lilly falsely claimed that it expected the chronic pain indication to gain FDA approval in 2009.

c. Lilly provided sales representatives with slanted "Verbatim's" to respond to physician inquiries about the latest adverse FDA actions or adverse news about Cymbalta. For instance, Lilly issued a "Verbatim" for sales representative use in response to Dr. Thomas Hardy et al 2007 article suggesting that treatment with Duloxetine for neuropathic pain impacts glycemic control.

66. To enhance the off-label promotion, the Lilly created additional sales forces:

a. In late 2007, it implemented a DPNP Representative (called "Pain Focused Rep") and placed one in most districts.

b. In addition, Lilly engaged contract sales representatives through a subsidiary of Quintiles Transactional Corporation, called NovaQuest, in order to quickly mobilize an additional sales force to market Cymbalta to pain physician targets. According to a Q4 2008 Earnings conference call, Lilly has been paying Quintiles a 8.25% royalty on Cymbalta.

c. In 2008, the cardiology sales force for a short period of time was also marketing Cymbalta.

67. Lilly also re-organized in part. In 2007, the Cymbalta Brand Team separated its organization of Cymbalta marketing into two district parts: pain and mood.

68. Lilly gave the sales force the incentive and the tools to market off-label:

a. The sales force was given credit for every prescription of Cymbalta, not just

on-label prescriptions.

b. The sales force was required by Lilly to participate in and to graduate from a home study course followed by a 3 and one half week training course at Lilly's corporate headquarters in Indianapolis, Indiana. In doing so, Relator and colleagues received training from Lilly corporate training officials on subjects such as how to induce physicians to ask "unsolicited" questions about Cymbalta off-label uses and to focus the marketing message on symptoms and behaviors, and to tell physicians about Cymbalta's superior efficacy in alleviating pain by working/affecting the descending pain pathway which, according to Lilly training, its speakers and detail pieces, extends from the brain throughout the spinal cord.

c. Lilly reinforced this training by providing mandatory role playing sessions designed to replicate what the sales person would experience in the field when calling on pain physicians.

d. Among other things, Lilly salespersons including Relator, engaged in role playing exercises that emulated physician sales calls.

e. Relator, having worked in the pharmaceutical sales prior to Lilly, vocally questioned the Lilly managers about the legality of the marketing practices being taught, specifically he questioned the off-label nature of the Cymbalta marketing campaign promoting Cymbalta's safety and efficacy for chronic pain to physicians. Relator was assured that by following Lilly's training on how to deliver the Cymbalta pain message, off-label regulations would not be violated.

f. In addition to communicating such practices during frequent regional and district sales conferences. Lilly engrained its off-label marketing message during annual national sales meetings, Division, Area and District meetings, and other specific gatherings.

g. Once out on the field, Relator was given Cymbalta marketing materials and "detail aids" useable for selling Cymbalta in the chronic pain market. Lilly's Cymbalta sales materials were the creation of the Cymbalta Brand Team, the division within Lilly responsible for developing the marketing and promotional selling message for Cymbalta in the United States.

h. Lilly sent the Relator and colleagues to Chicago in 2007 to become a "Certified Pain Representative" with the American Society of Pain Management. Most of the

meetings and course curriculum involved education about different pain states unrelated to Cymbalta indications. They also included a lot of off label discussion by Lilly paid doctors about Cymbalta. Other Lilly sales representatives and managers were present.

i. From about the summer of 2007 until the launch of Cymbalta's, in anticipation of FDA approval of Fibromyalga indication, at various meetings (District, Area & National) multiple DM's from multiple district's would meet with the representatives to rehearse and press the importance of off-label pain marketing. Managment would send the specialty reps to different rooms to meet and and rehearse, sometimes with different districts. In this regard, Relator not only met with his DM, Jim Delisle, but also Deb Shelton (Jax/Daytona), Robert Dugan (Orlando, "Cymbalta Pain Champ"). Relator knows of other Lilly reps in Florida under different managers as well as other Lilly reps in different parts of the country that were undergoing the same process.

j. Lilly monitored the success of the off-label promotional program by carefully monitoring sales revenues of each sales representative and setting high sales goals expected to be met as an ostensible measure of job performance. This includes rewarding sales representatives for off-label as well as on-label prescriptions. The sales force received IMS flash data (weekly) listing every physician who wrote any of their drugs, and also received information quarterly, called the "Quarterly Dashboard." The sales force also received a Neuroanalysis Tool, which provided rankings of physicians, losers and gainers on each drug.

k. Lilly bestowed sales representatives with large budgets to expend upon physicians to maintain and expand Cymbalta's chronic pain off-label market and resulting extraordinary revenues. In his first 6 months with Lilly, Relator was furnished with over $100,000 in program monies to spend on physicians, and did.

l. Lilly facilitated the use of physician speakers to further carry its message. Relator had just over 100 physician-targets in his District and about 5-6 were paid speakers. All except one of them earned the maximum yearly cap (set by Lilly) of $120,000 (one-hundred twenty thousand dollars) in 2006, and 2007, $90,000 (ninety thousand dollars) in 2008. There were also ways to get around the cap, as one of the Relator's physicians earned an extra $30,000 for "consultation with the Brand Team." (Speakers were paid $1000, $1,500, or $2,000 for each

engagement. Representatives are encouraged to get the good speakers to their cap amounts.)

m. At physician speaker meetings there were no corrections or admonitions by anyone on behalf of Lilly if speakers deviated from on-label discussion. Moreover, additional slides which suggested or prompted off-label use were presented by physician-speakers with no oversight by Lilly. In late 2008, the home office did send out a letter admonishing the sales force to better police the speakers, but it was never discussed or followed up on the District level.

n. Dinners were provided by Lilly to physicians for lavish amounts. It was not necessary to have a physician speaker for these events if there were 6 or less physician attendees.

o. Lilly management approved huge speaker fee budgets as a means to disguise large payments to physicians who were willing to prescribe Cymbalta off label. Lilly established large budgets for each representative to induce physicians to write off label. The speaking fees were from $1,000 to $2,000 for "peer-to-peer," "lunch and learn," as well as dinners with only one other physician present.

p. Physicians were even "groomed" by Lilly to be speakers by attending all expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market Cymbalta.

q. Sales representatives, including Relator, were instructed by Lilly on implementing "Peer-to-Peer Programs" intended on having paid physicians lecture on designated topics, including off-label topics. Lilly paid for the lavish meals/wine, etc. for all physicians in attendance. As long as a physician responded to the invite positively, then the physician could be factored into the total cost of the program in effect increasing the amount to be spent on any physician who attended. Also, non-prescribers, such as a kidney physician or lung physician, or any other Lilly sales force member, could attend and be paid for.

r. Sales representatives, including Relator, would be provided with small gifts to provide to physicians at the end of 20 minute web or teleconferences.

69. The Lilly Bureau even had a Form for phone consulting, where physicians could earn $700 to call another physician to discuss prescribing Cymbalta.

FEDERAL LAW PROHIBITS DRUG MANUFACTURERS FROM ENGAGING IN OFF-LABEL MARKETING TO PROTECT THE HEALTH AND SAFETY OF PATIENTS

70. A drug's FDA-approved uses and dosages are called the drug's "indication." "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (e.g. treating a child with the drug when the drug is approved to treat adults).

71. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21U.S.C. §360aaa(b) and (c).

72. Because of its inherent dangers, off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

73. Absent Lilly's unapproved, illegal off-label marketing, which included false representations, and its gifts to physicians, Cymbalta would not have been prescribed by physicians for off-label indications. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Government Healthcare Programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid.

74. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Government Healthcare Program regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the Federal and State False Claims Acts. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the Government Healthcare Programs is liable under the law.

75. The unwitting participation of the pharmacies in the submission of false claims was

not only foreseeable; it was an intended consequence of Lillys' scheme of fraud.

Claims Submitted to Government Healthcare Programs for Off-Label Uses Were Not Covered

76. In the Medicaid Program, states will not receive FFP ("Federal Financial Participation") if a drug, as prescribed, is not for a medically acceptable use. FFP is available to states only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). As a result, states' own laws and pharmacy regulations require that drugs must be used for a medically accepted use and therefore fit the definition of a covered outpatient drug.

77. "Covered outpatient drugs" do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. § 1396r-8(k). A medically accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" ("FDCA") or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. Id. § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(I) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System. The compendia will hereinafter be referred to collectively as "the Drug Compendia."

78. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e - 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting, and are "reasonable and necessary."

79. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting , and that are "reasonable and necessary.". 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517.

80. The Medicare program Part D drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k).

81. The off-label uses discussed herein were not covered by any of the Government Healthcare Programs. They are not supported by any legitimate clinical research, and could not, under any circumstances, be determined to be "medically accepted as safe and effective" or "reasonable and necessary"for such uses or supported by the compendia set forth in 42 U.S.C. § 1396r-8(k) for such uses. Claims for such off-label uses were therefore not covered by Government Healthcare programs.

82. Lilly was aware that the natural and probable consequence of its promotion of off-label uses of Cymbalta, was that health care providers would submit claims for payment to Government Healthcare Programs for the off-label uses.

83. Notwithstanding this knowledge, Lilly illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted these off-label uses. Lilly was aware that its illegal promotion did in fact result in false claims to these and other government payors for the off-label uses. Lilly was aware that its promotion activities was a substantial factor in producing the claims.

84. When pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for the off-label uses, the claims they submitted were false because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I), (Medicaid) not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective"or "reasonable and necessary." (Medicare) and not covered by other Government Healthcare Programs, See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

85. Since Lilly cannot submit claims directly to Government Healthcare Programs, it intentionally defrauded physicians to prescribe Cymbalta by engaging in a nationwide materially misleading off-label marketing campaign for the intended and foreseeable effect of causing

physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

86. False claims to these government healthcare programs for off-label prescribing was the direct and proximate result of unlawful off-label marketing efforts by Lilly. Lilly caused the submission of these claims.

87. Lilly caused the submission of false claims, since healthcare providers submitted Pharmacy Claim Forms and CMS-1500 Forms to Government Healthcare Programs, and the states submitted Form CMS-64 to the Federal Government, all claiming reimbursement for Cymbalta for such off-label uses.

COUNT 1

FALSE CLAIMS ACT

88. Relator realleges and incorporate by reference paragraphs 1 through 88 as though fully set forth herein.

89. This is a claim by Relator, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendant for knowingly causing to be presented false claims to Government Healthcare Programs. From on or about January 2002 through present, in the Northern District of California and elsewhere throughout the United States, Defendant has knowingly and willfully violated the False Claims Act by submitting and causing false claims to be submitted.

90. Defendant has knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment, knowing that such false claims would be submitted to state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for prescriptions induced by kickbacks and/or for non-covered uses and therefore false claims. By virtue of the acts described in this Complaint, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. §3729(a)(1) and 31 U.S.C. §3729(a)(2).

91. Defendant has violated 31 U.S.C. §3729(a)(2) by causing the states to submit false

claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Cymbalta, were paid for in compliance with federal law. States submitted false claims to the United States Government because when Cymbalta, was prescribed off-label, it was not prescribed for a medically accepted indication, yet states sought reimbursement from the United States Government for all Cymbalta expenditures.

92. Defendant caused false claims to be submitted, resulting in Government Program reimbursement to healthcare providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. §3729 et. seq. and the Anti-Kickback Act 42 U.S.C. §1320a-7b(b)(2)(A).

93. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

94. WHEREFORE, Relator respectfully requests this Court enter judgment against Defendant, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq. provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendant caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT II

CALIFORNIA FALSE CLAIMS ACT

95. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

96. This is a *qui tam* action brought by Relator on behalf of the State of California to

recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 et seq.

97. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
> ...
> (8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

98. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

99. Defendant violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the conduct described herein.

100. Defendant furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

101. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

102. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition

of payment of claims submitted to the State of California in connection with Defendant's conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

103. Had the State of California known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

104. As a result of Defendant's violation of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

105. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

106. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendant's conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendant presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT III

DELAWARE FALSE CLAIMS AND REPORTING ACT

107. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

108. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

109. 6 Del. C. § 1201(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

110. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

111. Defendant violated 31 Del. C. § 1005 by engaging in the conduct described herein.

112. Defendant furthermore violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

113. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

114. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition

of payment of claims submitted to the State of Delaware in connection with Defendant's conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

115. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

116. As a result of Defendant's violation of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

117. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of themselves and the State of Delaware.

118. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IV

FLORIDA FALSE CLAIMS ACT

119. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

120. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

121. Fla. Stat. § 68.082(2) provides liability for any person who-

> (a) knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

122. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;
>
> * * *
>
> (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

123. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

124. Defendant violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

125. Defendant furthermore violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

126. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

127. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendant's conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

128. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

129. As a result of Defendant's violation of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

130. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of themselves and the State of Florida.

131. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendant:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Florida
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of' law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT V

GEORGIA FALSE MEDICAID CLAIMS ACT

132. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

133. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) *et seq.*

134. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

135. Defendant violated O.C.G.A. § 49-4-168 *et seq.* by engaging in the conduct described herein.

136. Defendant furthermore violated O.C.G.A. § 49-4-168 and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for

reimbursement by the government-funded healthcare programs.

137. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

138. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendant's conduct. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

139. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

140. As a result of Defendant's violation of O.C.G.A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

141. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of herself and the State of Georgia.

142. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VI

HAWAII FALSE CLAIMS ACT

143. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

144. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.

145. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

146. Defendant violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

147. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

148. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendant's conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

149. Had the State of Hawaii known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

150. As a result of Defendant's violation of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

151. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.

152. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendant's illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VII

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

153. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

154. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175 *et seq.*

155. 740 Ill. Comp. Stat. 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

156. In addition, 305 Ill. Comp. Stat. 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

157. Defendant violated 305 Ill. Comp. Stat. 5/8A-3(b) by engaging in the conduct described herein.

158. Defendant furthermore violated 740 Ill. Comp. Stat. 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

159. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare

providers and third party payers in connection therewith.

160. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendant's conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

161. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

162. As a result of Defendant's violation of 740 Ill. Comp. Stat. 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

163. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 Ill Comp. Stat. 175/3(b) on behalf of herself and the State of Illinois.

164. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 Ill. Comp. Stat.175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VIII

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

165. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

166. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq*. provides:

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)...

167. In addition, Indiana Code 5-11-5.5 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Indiana Medicaid program.

168. Defendant violated the Indiana Code 5-11-5.5 *et seq.* by engaging in the conduct described herein.

169. Defendant furthermore violated Indiana Code 5-11-5.5 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Indiana

Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

170. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

171. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendant's conduct. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

172. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

173. As a result of Defendant's violation of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

174. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of themselves and the State of Indiana.

175. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendant's conduct;

(2) A Civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the State of Indiana;

(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX

LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

176. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

177. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46: 437.1 *et seq.*

178. La. Rev. Stat. 46: 438.3 provides-

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

179. In addition, La. Rev. Stat. 46: 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the Louisiana medical assistance programs.

180. Defendant violated La. Rev. Stat. 46: 438.2(A) by engaging in the conduct described herein.

181. Defendant furthermore violated La. Rev. Stat. 46: 438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. 456: 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

182. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

183. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendant's conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

184. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

185. As a result of Defendant's violation of La. Rev. Stat. 46: 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

186. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. 46: 439.1(A) on behalf of themselves and the State of Louisiana.

187. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendant's conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendant caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X

MICHIGAN MEDICAID FALSE CLAIMS ACT

188. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

189. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

> 400.603 provides liability in pertinent part as follows:
> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits;
> (2)A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit...

190. In addition, MI ST Ch. 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Michigan Medicaid program.

Defendant violated MI ST Ch. 400.603 *et seq.* by engaging in the conduct described herein.

191. Defendant furthermore violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

192. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

193. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendant's conduct. Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an

express condition of payment of claims submitted to the State of Michigan.

194. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

195. As a result of Defendant's violation of MI ST Ch. 400.603 *et seq.* the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

196. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to MI ST Ch. 400.603 *et seq.* on behalf of themselves and the State of Michigan.

197. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendant's conduct;
(2) A civil penalty equal to the full amount received for each false claim which Defendant caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI

MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. § 17-8-403(1)(a)-(b)

198. Plaintiff realleges and incorporates by reference the allegations contained in

paragraphs 1 through 88 above as if fully set forth herein.

199. This is a qui tam action brought by Relator on behalf of the State of Montana to recover treble damages and penalties under the Montana False Claims Act, Mont. Code Ann § 17-8-403(1)(a)-(b).

200. 17-8-403 provides liability for any person who:

> (a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
> (b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;
> (c) conspiring to defraud the governmental entity by getting false claim allowed or paid by the governmental entity.
> (h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

201. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendant's conduct. Compliance with applicable Montana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Montana.

202. Had the State of Montana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

203. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's conduct.

204. By reason of the Defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

205. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Montana:

(1) Not less than two times and not more than three times the amount of actual damages which the State of Montana has sustained as a result of Defendant's conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendant caused to be presented to the State of Montana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Montana Code Ann. § 17-8-403(1)(A)-(B). and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII

NEVADA FALSE CLAIMS ACT

206. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

207. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010, *et. seq.*

208. Nev. Rev. Stat. § 357.040(1) provides liability for any person who-

(a) knowingly presents or causes to be presented a false claim for payment or approval;
(b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim
(c) conspires to defraud by obtaining allowance or payment of a false claim;
(h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

209. In addition, Nev. Rev. Stat. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

210. Defendant violated Nev. Rev. Stat. § 422.560 by engaging in the conduct described herein.

211. Defendant furthermore violated Nev. Rev. Stat.§ 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and Nev. Rev. Stat. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

212. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

213. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendant's conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

214. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

215. As a result of Defendant's violation of Nev. Rev. Stat. § 357.040(1) the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

216. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of themselves and the State of Nevada.

217. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to

the following parties and against Defendant:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to Nev. Rev. Stat. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII

THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT

218. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

219. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev.Stat. Ann§167:61-b *et seq.* provides:

220. 1. Any person shall be liable who...

(a) knowingly presents, or causes to be presented, to an officer or employee of the department a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
(f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim

221. In addition, N.H. Rev.Stat. Ann. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Hampshire Medicaid program.

222. Defendant violated the N.H. Rev.Stat. Ann by engaging in the conduct described herein.

223. Defendant furthermore violated N.H. Rev.Stat. Ann. §167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New Hampshire Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

224. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

225. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Defendant's conduct. Compliance with applicable New Hampshire statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Hampshire.

226. Had the State of New Hampshire known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

227. As a result of Defendant's violation of N.H. Rev.Stat. Ann. §167:61-b *et seq.*, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

228. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b *et seq.* on behalf of themselves and the State of New Hampshire.

229. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to

the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of New Hampshire:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of New Hampshire;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV

NEW JERSEY FALSE CLAIMS ACT

230. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

231. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.* (2008) *et seq.*

232. N.J. Stat. § 2A:32C-3 provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an employee, officer, or agent of the State or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

233. In addition, Section 17 of P.L. 1968, c.413 (C.30:4D-17) of the New Jersey False Claims Act prohibits the solicitation, offer or receipt of any remuneration, including any kickback,

rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program.

234. Defendant violated Section 17 of P.L. 1968, c.413 (C.30:4D-17) by engaging in the conduct described herein.

235. Defendant furthermore violated N.J. Stat. § 2A:32C-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New Jersey False Claims Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

236. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

237. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendant's conduct. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.

238. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

239. As a result of Defendant's violation of N.J. Stat. § 2A:32C-1 *et seq.*, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

240. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 *et seq.* on behalf of herself and the State of New Jersey.

241. This Court is requested to accept pendant jurisdiction of this related state claim as it

is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 *et seq.*) which Defendant caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV

NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

242. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

243. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act N.M. Stat. Ann§§ 27-14-1 *et seq.*

244. Section 4 provides liability in pertinent part as follows:
A person ...shall be liable...if the person:
A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
B. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid for or approved by the state knowing such record or statement is false;

> D. conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent;

245. It is also brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 *et seq.* provides liablity in pertinent part as follows:

246. § 44-9-3(A) A person shall not:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim;

247. In addition, N.M. Stat. Ann§§ 30-44-7 *et seq.* prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Mexico Medicaid program.

248. Defendant violated N.M. Stat. Ann§§ 30-44-7 et seq by engaging in the conduct described herein.

249. Defendant furthermore violated, N.M. Stat. Ann§§ 27-14-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

250. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

251. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendant's conduct.

Compliance with applicable New Mexico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.

252. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

253. As a result of Defendant's violation of N.M. Stat. Ann§§ 27-14-1 *et seq.* the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

254. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* on behalf of themselves and the State of New Mexico.

255. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI

NEW YORK FALSE CLAIMS ACT

256. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

257. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII

258. Section 189 provides liability for any person who:

> 1.(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
> 1. (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
> 1. (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

259. In addition, the New York State Consolidated Laws prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New York Medicaid program.

260. Defendant violated the New York State Consolidated Laws by engaging in the conduct described herein.

261. Defendant furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the New York Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

262. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

263. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendant's conduct. Compliance with applicable New York statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New York.

264. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

265. As a result of Defendant's violation of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

266. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of themselves and the State of New York.

267. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendant caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII

OKLAHOMA MEDICAID FALSE CLAIMS ACT

268. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

269. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq.*

270. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

271. In addition, 56 Okl. St. § 1005 (2008) of the Oklahoma Medicaid Program Integrity Act prohibits the solicitation or receipt of any benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

272. Defendant violated 56 Okl. St. § 1005 *et seq.* by engaging in the conduct described herein.

273. Defendant furthermore violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Oklahoma Medicaid Program Integrity Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

274. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

275. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendant's conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

276. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

277. As a result of Defendant's violation of 63 Okl. St. § 5053.1 *et seq.*, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

278. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 *et seq.* on behalf of herself and the State of Oklahoma.

279. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII

RHODE ISLAND STATE FALSE CLAIMS ACT

280. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

281. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I.Gen. Laws § 9-1.1-1 (2008) *et seq.*

282. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

283. In addition, R.I. Gen. Laws § 40-8.2-3(2)(i) prohibits the solicitation, receipt, offer or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Rhode Island Medicaid program.

284. Defendant violated R.I. Gen. Laws § 40-8.2-3 *et seq.* by engaging in the conduct described herein.

285. Defendant furthermore violated R.I.Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Rhode Island General Laws and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

286. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by

healthcare providers and third party payers in connection therewith.

287. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendant's conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

288. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

289. As a result of Defendant's violation of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

290. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 *et seq.* on behalf of herself and the State of Rhode Island.

291. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIX

TENNESSEE FALSE CLAIMS ACT

292. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

293. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

294. § 4-18-103(a) provides liability for any person who-

> (1) Knowingly presents, or causes to be presented to an officer or employee of the state..., a false claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) Conspires to defraud the state or any political subdivision by getting a claim allowed or paid by the state of by any political subdivision.

§ 71-5-182(a)(1) provides liability for any person who-

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

295. Defendant violated Tenn. Code Ann. § 4-18-103(a) and § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

296. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by

healthcare providers and third party payers in connection therewith.

297. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendant's conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

298. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

299. As a result of Defendant's violation of Tenn. Code Ann. § 4-18-103(a) and § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

300. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 4-18-103(a) and § 71-5-183(a)(1) on behalf of themselves and the State of Tennessee.

301. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX

TEXAS MEDICAID FRAUD PREVENTION LAW

302. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

303. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001 *et seq.*

304. Tex. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit

(2) knowingly or intentionally concealing or failing to disclose an event:
(A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
(i) the person, or
(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
(B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
(B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

305. Defendant violated Tex. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

306. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

307. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendant's conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

308. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

309. As a result of Defendant's violation of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

310. Defendant did not, within 30 days after it first obtained information as to such violation, furnish such information to officials of the State responsible for investigating false claims violation, did not otherwise fully cooperate with any investigation of the violation, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

311. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of themselves and the State of Texas.

312. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to

the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 or more than $15,000 pursuant to Tex. Hum.. Res. Code § 36.025(a)(3) for each false claim which Defendant cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI

WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

313. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

314. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.*

315. Wis. Stat. § 20.931(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
(c) conspires to defraud this State by obtaining allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
(g) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any

> obligation to pay or transmit money or property to the Medical Assistance Program.

316. In addition, Wis. Stat. § 49.49(2) of the Wisconsin Public Assistance Code prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Wisconsin Medicaid program.

317. Defendant violated Wis. Stat. § 49.49(2) by engaging in the conduct described herein.

318. Defendant furthermore violated Wis. Stat. § 20.931 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Wisconsin Public Assistance Code and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

319. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

320. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendant's conduct. Compliance with applicable Wisconsin statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Wisconsin.

321. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

322. As a result of Defendant's violation of Wis. Stat. § 20.931 *et seq.* , the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

323. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 *et seq.* on behalf of

herself and the State of Wisconsin.

324. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Wisconsin;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXII

MASSACHUSETTS FALSE CLAIMS ACT

325. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

326. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of

Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Chap. 12 § 5(A) *et seq.*

327. Mass. Gen. Laws Chap. 12 § 5B provides liability for any person who-

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or ...
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim shall be liable to the commonwealth or political subdivision.

328. In addition, Mass. Gen. Laws Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

329. Defendant violated Mass. Gen. Laws Chap. 118E § 41 by engaging in the conduct described herein.

330. Defendant furthermore violated Mass. Gen. Laws Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

331. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

332. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief: also an express condition

of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendant's conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

333. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

334. As a result of Defendant's violation of Mass. Gen. Laws Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

335. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

336. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

337. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

338. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Va. Code Ann. § 8.01-216.3a provides liability for any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

339. In addition, Va. Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Virginia Medicaid program.

340. Defendant violated Va. Code Ann. § 32.1-315 by engaging in the conduct described herein.

341. Defendant furthermore violated Va. Code Ann. § §8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, VA Code ANN § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

342. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

343. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendant's conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

344. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

345. As a result of Defendant's violation of Va. Code Ann. §8.01-216.3(A), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

346. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.3 on behalf of themselves and the Commonwealth of Virginia.

347. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Va. Code Ann. § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

348. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

349. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

350. D.C. Code § 2-308.14(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to: be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
> (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

351. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program, or
> (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

352. Defendant violated D.C. Code § 4-802(c) by engaging in the illegal conduct described herein.

353. Defendant furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

354. The District of Columbia, by and through the District of Columbia Medicaid program

and other state healthcare programs, and unaware of Defendant's illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

355. Compliance with applicable Medicare, Medicaid and the various other federal and stale laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the District of Columbia in connection with Defendant's illegal conduct. Compliance with applicable D.C. statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.

356. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Cymbalta, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

357. As a result of Defendant's violation of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

358. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of themselves and the District of Columbia.

359. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendant's illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the District of Columbia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

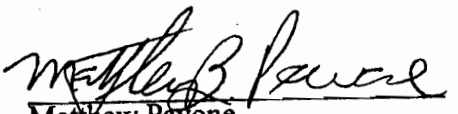
To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

DATED: May 1, 2009.

NOLAN & AUERBACH, P.A.

By: 

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